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Tornqvist

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(54) **DEVICE, SEALING MEMBER AND FLUID CONTAINER**

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A61M 39/10	(2006.01)

(52) **U.S. Cl.**

CPC ***A61M 5/162*** (2013.01); ***A61J 1/20*** (2013.01); ***A61M 39/1011*** (2013.01); *A61J 1/201* (2015.05); *A61J 1/2055* (2015.05)

(58) **Field of Classification Search**

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See application file for complete search history.

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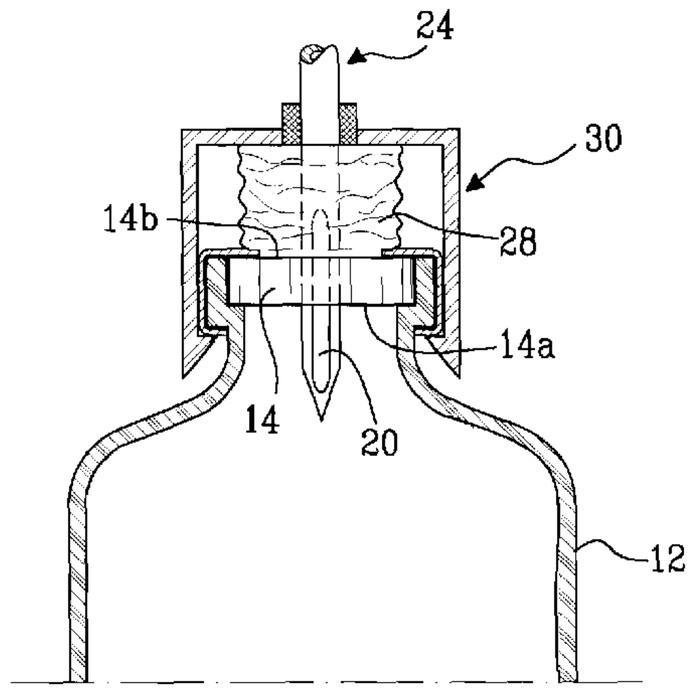
(57) **ABSTRACT**

A device for transferring a fluid to and/or from a fluid container having a sealing member. The device includes a piercing member for penetrating the sealing member and an elongated body defining a longitudinal flow channel through which a fluid may flow into and/or out of the fluid container and at least one opening that communicates with the flow channel. The at least one opening is arranged to extend along at least 1% of the length (l) of the piercing member to ensure that at least part of the at least one opening (**20**) is located substantially adjacent to the innermost side of a sealing member when the device is in use.

19 Claims, 3 Drawing Sheets



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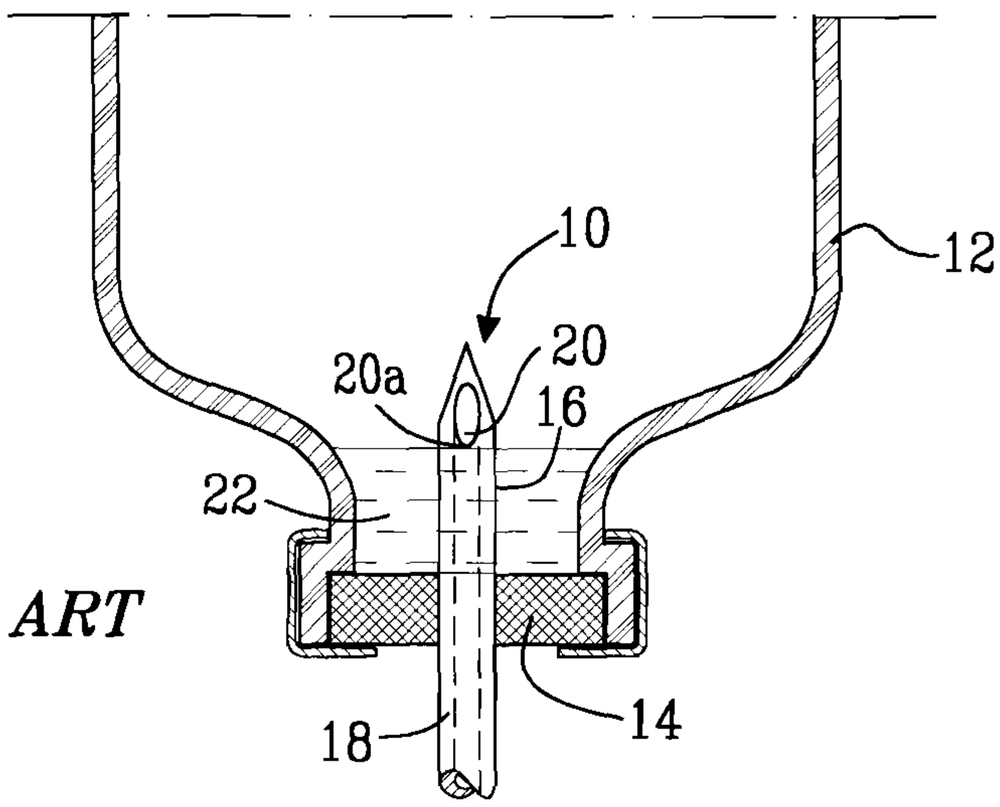

PRIOR ART

Fig. 1

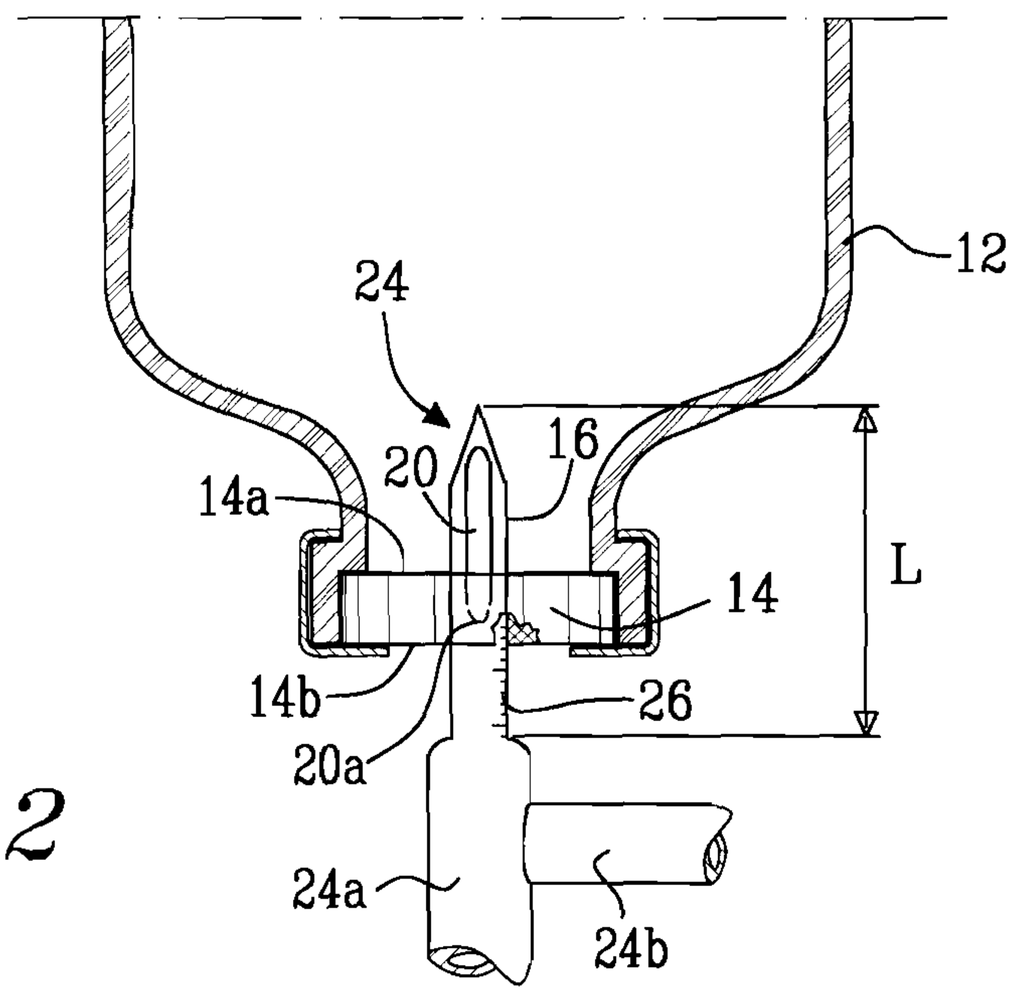

Fig. 2

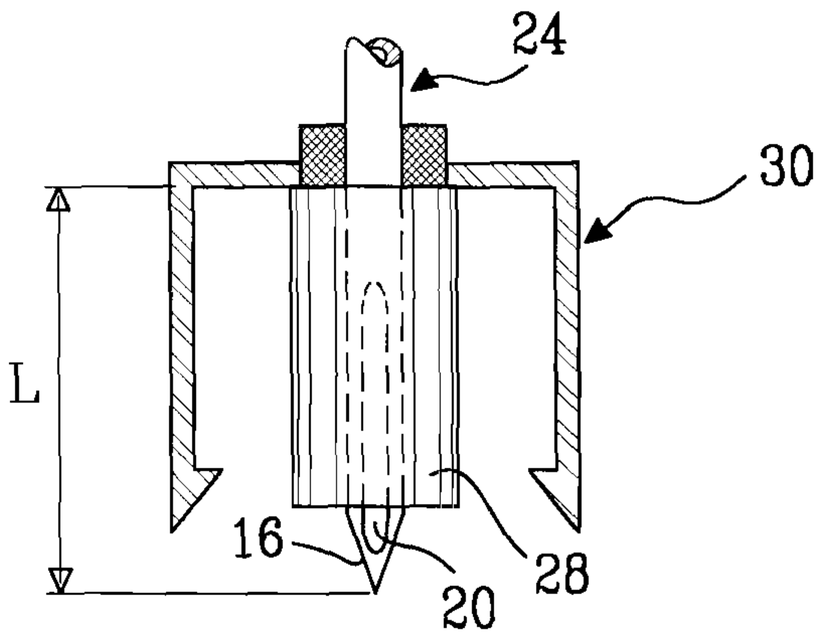

Fig.3

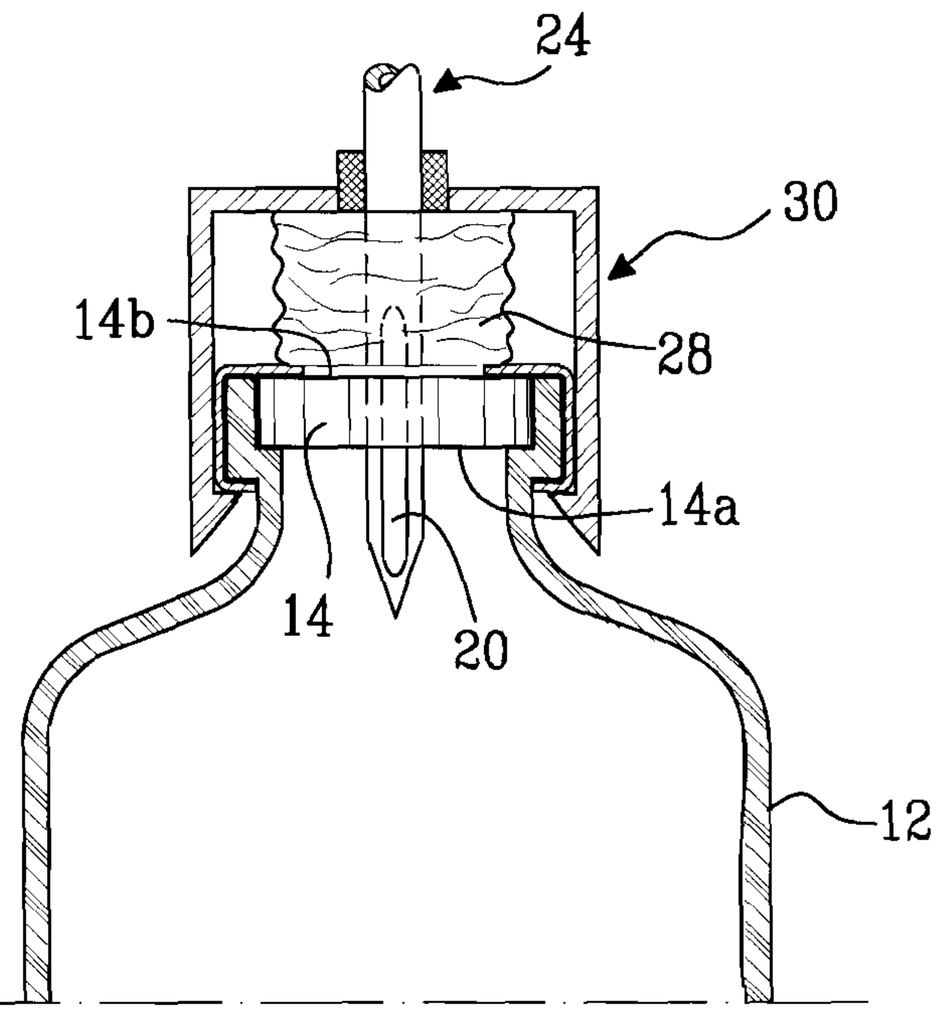

Fig.4

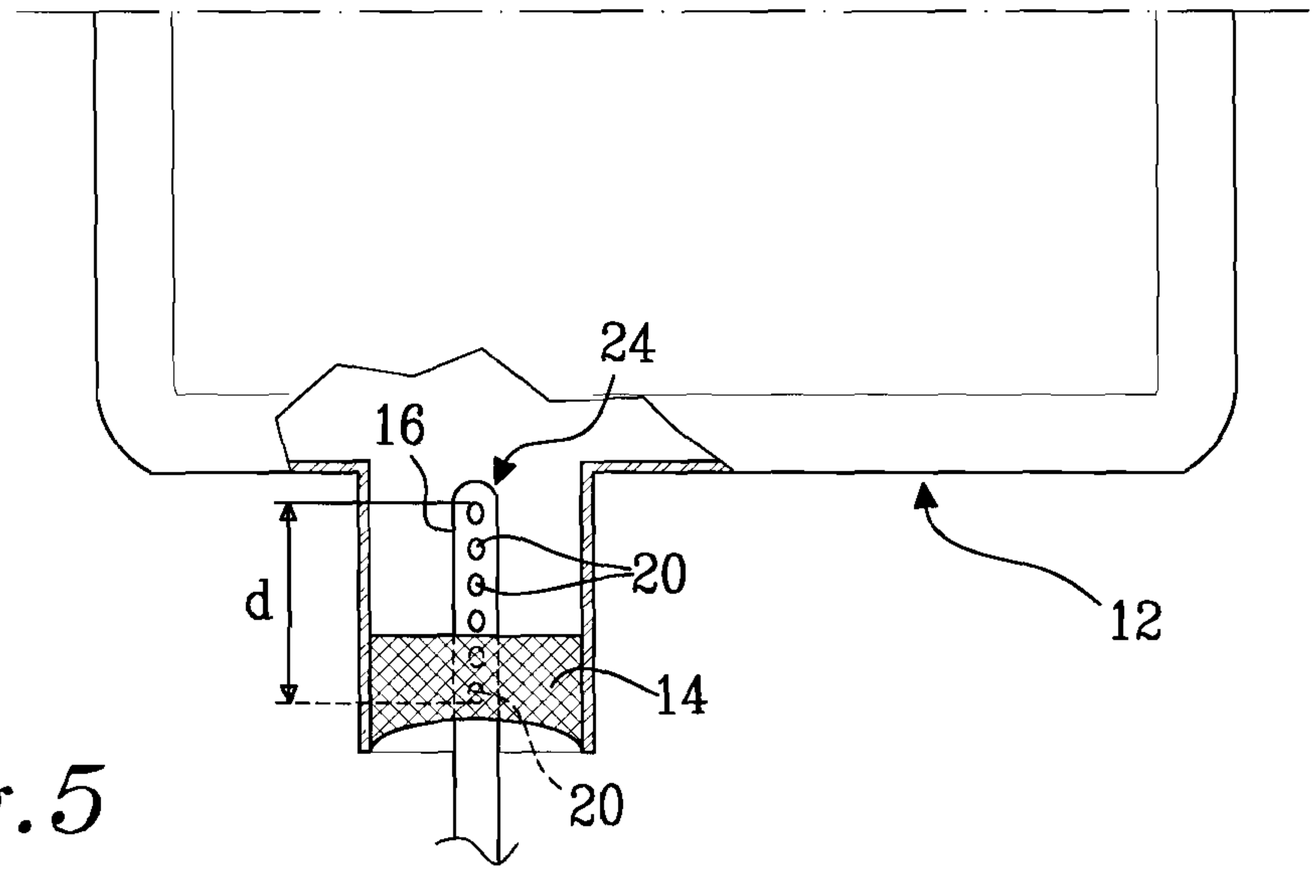

Fig.5

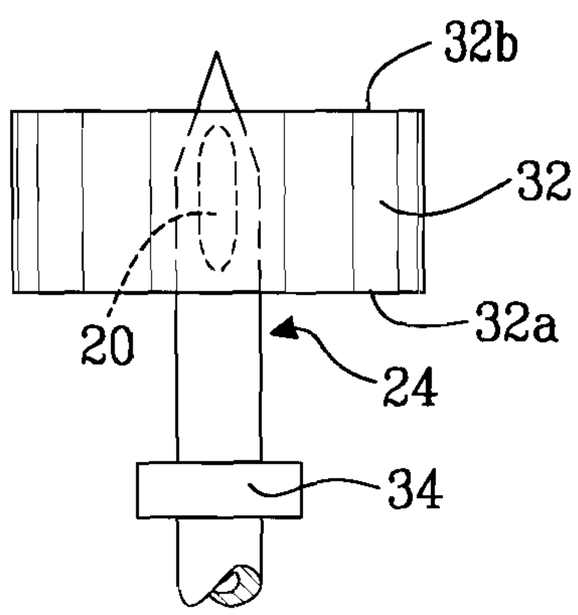

Fig.6

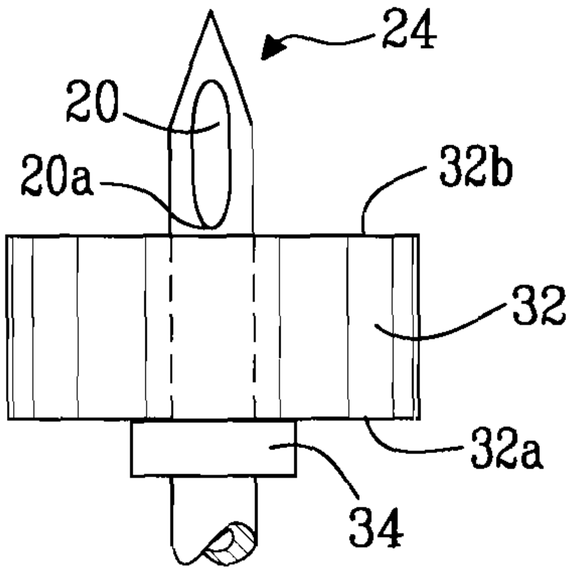

Fig.7

DEVICE, SEALING MEMBER AND FLUID CONTAINER

TECHNICAL FIELD

The present invention concerns a device for transferring a fluid to and/or from a fluid container having a sealing member. The present invention also concerns a sealing member and a fluid container. The device, sealing member and fluid container of the present invention are particularly, but not exclusively intended for transferring medical substances to and/or from a fluid container, however they may be used for transferring any kind of fluid, i.e. any continuous, amorphous substance whose molecules move freely past one another and that has the tendency to assume the shape of its container, to and/or from a fluid container.

BACKGROUND

Medical drugs and solvents are often supplied in glass or plastic containers, such as vials, bottles or bags, which are sealed by a rubber, plastic or elastomeric bung, stopper, membrane or puncturable cap. Such sealing members prevent deterioration or contamination of the drug, allow the contents of a container to be mixed by shaking, and prevent the contents of the container from leaking out and contaminating the surroundings. A cannula or a hollow spike comprising a flow channel and an opening that communicates with the flow channel, is usually inserted through such a sealing member to supply fluids to the container and to withdraw fluid therefrom.

If an infusion fluid container is made of a rigid or semi-rigid material, i.e. if its walls are non-collapsible, an air inlet is required to withdraw medical fluid from the infusion fluid container and prevent the formation of a vacuum therein. When withdrawing fluid from a rigid or semi-rigid infusion fluid container, a spike having a medical fluid flow channel and an air inlet passage, usually comprising an air filter, is therefore used.

When a container comprising medical fluid is nearly empty a cannula or spike is often used to withdraw the last few drops of the medical fluid (which may be very expensive and/or toxic) from the container to minimize waste and to facilitate cleaning/disposal of the container. The cannula or spike is slowly and carefully retracted through the sealing member while withdrawing the medical fluid remaining in the container. However, a toxic drug may leak out and contaminate the surroundings during such a procedure and non-filtered air containing undesirable particles such as dust, pollen or bacteria may be drawn into the cannula and thus contaminate the medical fluid therein.

In some cases containers are in fact provided with an extra amount of the drug that is to be withdrawn to allow for the fact that not all of the drug will be withdrawn from the container. A user is then able to withdraw the recommended number of doses from the container but doing so will increase the cost of each container of medical fluid, increase waste and make cleaning or disposal of the container more complex.

Since sealing members are available in a wide variety of configurations, sizes and thicknesses, it is difficult to design a spike that is suitable for use with a plurality of different sealing members and which makes it possible to withdraw the last few drops of a medical fluid out of the containers in a safe and convenient way.

SUMMARY OF THE INVENTION

One aspect of the invention features a device that enables an efficient transfer of fluid into and/or out of a fluid container having a sealing member.

According to one embodiment, a device comprises a piercing member for penetrating the sealing member and an elongated body defining a longitudinal flow channel through which a fluid may flow into or out of the fluid container. The device comprises at least one opening that communicates with the flow channel whereby the at least one opening is arranged to extend along at least 1% preferably at least 2%, or at least 3%, or at least 4%, or at least 5%, or at least 10%, or at least 20%, or at least 30%, or at least 50% or most preferably at least 70% or 100% of the length of the piercing member to ensure that at least part of the at least one opening is located substantially adjacent to the innermost side of a sealing member when the device is in use.

The length of the piercing member is defined as the distance from the tip of the piercing member to the point at which the width of the device increases by an amount that would require a substantially increased force to push that part of the device more deeply into an infinitely wide sealing member of a bottomless fluid container. In cases where the device has a substantially uniform cross section along its entire length, the length of the piercing member is defined as the distance from the tip of the piercing member to opposite end of the device.

Such a device allows the entire contents, or essentially the entire contents of the fluid container to be drained from an inverted fluid container.

The inventive device also improves the mixing of fluids inside the container when the fluid container is inverted or in an upright position. If a liquid drug is to be mixed with a liquid solvent in an inverted or upright fluid container, for example, the mixing of the two liquids is facilitated since a plurality of openings or an elongated opening allows a liquid drug/solvent to flow into the fluid container more quickly than if using a conventional device and mixing is improved due to the increased and more distributed inlet area and the increased turbulence caused thereby.

Furthermore, if the fluid container and its contents have been refrigerated, if a fluid having a higher temperature than the contents of the fluid container is supplied through the sealing member of an inverted fluid container, convection currents may speed up the mixing of the two fluids. Convection currents may also aid mixing if a refrigerated fluid enters the top of an upright fluid container containing a fluid having a higher temperature than the refrigerated fluid.

The inventive device is suitable for use with a plurality of fluid containers comprising sealing members of different thicknesses (which can range from a few millimeters to a few centimeters) and different configurations (such as concave, biconcave or M-shaped) if the at least one opening extends over a length that is greater than the thickness of the thickest sealing member that the device is designed to penetrate.

According to an embodiment of the invention the device comprises one opening that extends substantially along the entire length of the piercing member.

According to another embodiment of the invention the device comprises a plurality of openings that are uniformly or non-uniformly spaced along the length of the piercing member.

According to a further embodiment of the invention the device comprises a retractable sleeve, such as a rubber, plastic or elastomeric sheath, that is arranged to at least

partially cover and seal the at least one opening before the device is inserted into the sealing member of a fluid container. The retractable sleeve is arranged to abut against the outermost side of the sealing member when the device has been inserted into a sealing member of a fluid container and retract as the piercing member penetrates more deeply into the sealing member so that it will cover and seal only the part of the opening, or the openings that are located outwards of the outermost side of the sealing member when the device is in use and thus prevent any medical fluid from leaking out of that opening or those openings.

According to an embodiment of the invention the device comprises connecting means to connect it to a fluid container so that the device will not accidentally become detached from the fluid container when the device is in use, or prior to or after use.

According to an embodiment of the invention, the device comprises a ruled scale, which for example extends from the outermost edge of an opening in the direction from the interior of the fluid container outwards towards the sealing member. If the thickness of a sealing member at the point of insertion of the device is known, the ruled scale may be used to indicate to a user how far the device has to be inserted into the sealing member to ensure that the outermost edge of the opening becomes located substantially adjacent to the innermost side of a sealing member when the device is in use. The ruled scale may also be used to measure the thickness of the sealing member before the device is inserted into it.

The present invention also concerns a sealing member, such as a rubber, plastic or elastomeric bung, stopper, membrane or puncturable cap, for sealing an outlet of a fluid container, which sealing member comprises a device according to any of the embodiments of the invention whereby the device is integrally formed with the sealing member or releasably/non-releasably connected thereto.

According to an embodiment of the invention the device is slidably mounted on the sealing member so that the at least one opening of the device may be opened and closed by sliding the device back and forth with respect to the sealing member.

The present invention further concerns a fluid container that comprises a sealing member according to any of the embodiments of the invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will hereinafter be further explained by means of non-limiting examples with reference to the appended figures where;

FIG. **1** shows a conventional device for transferring fluid to and/or from a fluid container,

FIGS. **2-5** show devices for transferring fluid to and/or from a fluid container according to embodiments of the invention, and

FIGS. **6-7** show sealing a sealing member according to an embodiment of the invention.

It should be noted that the drawings have not been drawn to scale and that the dimensions of certain features have been exaggerated for the sake of clarity.

Furthermore, it should be noted that irrespective of whether a rigid, semi-rigid or flexible fluid container is exemplified in the appended figures, the present invention is suitable for use with any type of fluid container having a sealing member.

DETAILED DESCRIPTION OF EMBODIMENTS

FIG. **1** shows a conventional device **10** for transferring fluid to and/or from an inverted fluid container **12** having a sealing member **14** that hermetically seals the contents **22** of the fluid container **12**. The device **10** comprises a piercing member **16** for penetrating the sealing member **14** and an elongated body defining a longitudinal flow channel **18** through which the contents of the fluid container may flow into and/or out of the fluid container **12** and one lateral opening that communicates with the flow channel **18**. Since sealing members **14** vary in thickness and toughness, the opening **20** of the device can become located at any of an infinite number of positions in the fluid container **12** depending on how much force the user applies when inserting the device **10** through the sealing member **14** and depending on whether the device is inserted substantially vertically or at an angle to the longitudinal axis of the fluid container **12**. Once the contents **22** of the fluid container **12** have drained to a level just under the outermost edge **20***a* of the opening, no more fluid will be able to drain from the fluid container unless the device is withdrawn slightly.

FIG. **2** shows a device **24** in accordance with the present invention for transferring a fluid to and/or from an inverted fluid container **12** having a sealing member **14**. The device **24** comprises a piercing member **16** having a bevelled tip for penetrating the sealing member **14** and may also optionally comprise an elongated tubular body portion **24***a* of any symmetrical or non-symmetrical cross-sectional form, such as circular, square, hexagonal or octagonal. The elongated body portion **24***a* has a greater width than the width of the piercing member **16** and is not intended to be inserted through the sealing member **14** of a fluid container **12**. The elongated body portion **24***a* may comprise a drop chamber. The device **24** may also optionally comprise an air/liquid inlet **24***b*.

The piercing member **16** defines a substantially longitudinal flow channel (not shown) through which the contents of the fluid container may flow into and/or out of the fluid container **12** and one elongated opening **20**, that can be of any shape, such as rectangular, square, circular or oval, which communicates with the flow channel. The opening **20**, extends longitudinally along about 50% of the length, L, of the piercing member **16**, either from the tip of the piercing member or a few millimeters from the tip of the piercing member, to ensure that at least part of the at least one opening is located substantially adjacent to the innermost side **14***a* of a sealing member **14** when the device **10** is in use. The maximum width of the opening **20** is equal to at least 20% of the maximum width of the piercing member **16**, preferably at least 50% of the maximum width of the piercing member **16**.

In the example shown, the innermost side **14***a* of the sealing member **14** overlaps the elongated opening **20** when the device is in use. The device **24** also comprises a ruled scale **26** to allow a user to accurately position the outermost edge **20***a* of the opening **20** if he/she knows the thickness of the sealing member **14** at the point of insertion of the device **24**.

The device **24** may comprise plastic, such as thermoplastic material; metal, glass or a ceramic material. The length of the piercing member **16** may range from 0.5-5.0 cm or more, whereby the length of the piercing member is preferably 5 to 20 times its maximum width.

It should be noted that although a rigid or semi-rigid fluid container **12**, such as a glass bottle, has been illustrated in FIG. **2**, the inventive device **24** is equally suitable for use with a non-rigid fluid container, such as an infusion bag. Furthermore, even though an air inlet would be necessary when draining fluid from a rigid or semi-rigid fluid container, air inlets and air channels have not been illustrated in

any of the drawings for the sake of clarity. The inventive device could however comprise any number of channels for air or other fluids.

FIG. **3** shows a device **24** according to another embodiment of the invention before the device has been inserted into the sealing member of a fluid container. The device comprises one opening **20** that extends substantially along the entire length, L, of the piercing member **16** from behind its solid beveled tip towards the opposite end of the piercing member **16**. The length of the opening **20** will of course depend on the thickness of the thickest sealing member **14** that it is intended to penetrate. The device **24** comprises a tightly fitting elastic retractable sleeve **28**, comprising silicone rubber for example, that is arranged to at least partially cover and seal the at least one opening **20** before the device is inserted into a fluid container. The retractable sleeve **28** is arranged to abut against the outermost side **14***b* of the sealing member **14** when the device has been inserted into a fluid container **12** and to retract as the piercing member **16** penetrates more deeply into sealing member **14**.

FIG. **4** shows the device **24** of FIG. **3** after it has been inserted into the sealing member **14** of a fluid container **12**. It can be seen that the part of the opening **20** inwards of the innermost side **14***a* of the sealing member **14** is exposed to the interior of the fluid container whereas the part of the opening **20** outwards of the outermost side **14***b* of the sealing member **14** is sealed, thereby preventing deterioration or contamination of the contents of the fluid container **12**, allowing the contents of a fluid container **12** to be mixed by shaking, and preventing the contents of the fluid container **12** from leaking out and contaminating the surroundings.

The device **24** shown in FIGS. **3** and **4** also comprises connecting means **30**, to grippingly engage the rim of the fluid container **12** to hold the device **24** firmly in place on the fluid container **12**. The connecting means **30** comprises two manually operable resilient arms comprising curved end regions that slidably engage the rim of the fluid container **12** when the device **24** has been pushed through the fluid container's sealing member **14**. The connecting means **30**, which may be a snap-fit mechanism, a luer lock or any other mechanical or non-mechanical connecting means, may be arranged to cause the piercing member **16** of the device to penetrate the sealing member **14** of a fluid container **12** as the connecting means are engaged, thus providing fluid communication between the interior of the fluid container **12** and the flow channel of the device **24**, i.e. fluid communication is provided when a luer lock is twisted into a locked position for example.

According to another embodiment of the invention, the device comprises a piercing member shield/guard to prevent users from being hurt by the piercing member **16** and to prevent contamination of the piercing member **16**. In the embodiment shown in FIGS. **3** and **4**, the connecting means **30** also act as a piercing member shield/guard.

It should be noted that the at least one opening **20** of the inventive device **24** need not necessarily extend in a direction parallel or collinear to the longitudinal axis of the device **24**, it/they may extend in a zig-zag pattern along the length of the piercing member **16** or even be constituted by a plurality of openings that extend transversely to the longitudinal axis of the device **24**.

FIG. **5** shows a device **24** according to a further embodiment of the invention. The device **24** comprises a plurality of openings **20** uniformly spaced along a distance d, which extents substantially along the entire length of the piercing member **16**. If the length of the piercing member is 3 cm, the device **24** may for example comprise ten uniformly spaced openings **20** that extend 2 mm along the longitudinal direction of the piercing member **16**, each thereby spaced 1 mm apart. In the illustrated embodiment the piercing member **16** comprises a blunt end, which may be used to pierce a sealing member **14** having a thin central portion, or to pierce a pre-slit sealing member **14**. It is to be understood, of course, that a pointed piercing member may also be used in relation to this embodiment.

FIGS. **6** and **7** show a sealing member **32** according to an embodiment of the invention. The sealing member **32** comprises natural or synthetic rubber or any other elastomer, plastic or glass for example. The sealing member **32** comprises a device **24** according to any of the embodiments of the invention whereby the device **24** is integrally formed with the sealing member **32** or releasably/non-releasably connected thereto. The device **24** is slidably mounted on the sealing member **32** so that the at least one opening **20** of the device may be opened and closed by sliding the device back and forth with respect to the sealing member from a closed position as shown in FIG. **6** to an open position as shown in FIG. **7**. The device **24** may of course be arranged to stop at any number of further positions in addition to the fully open and fully closed positions that have been illustrated.

In FIG. **7**, the entire piercing member **16** of the device **24** has been pushed through the sealing member **32** until a shoulder **34** on the device abuts against the outermost edge **32***a* of the sealing member **32**. In this position the lower edge **20***a* of the opening is aligned with the innermost edge **32***b* of the sealing member **32** so that the whole opening **20** will be exposed to the interior of the fluid container in which the sealing member **32** is inserted.

The inventive sealing member **32** may be inserted into the inlet/outlet of a fluid container **12** or may comprise means, such as a thread, to enable it to be attached to a fluid container for example.

Further modifications of the invention within the scope of the claims would be apparent to a skilled person.

The invention claimed is:

1. A device for transferring a fluid to a fluid container, or from a fluid container, or both to and from a fluid container, wherein said fluid container comprises a sealing member having an innermost side and an outermost side, the device comprising:

a piercing member having a tip for penetrating the sealing member;

an elongated body defining a longitudinal flow channel through which a fluid may flow into and/or out of the fluid container, the elongated body having a greater width than the width of the piercing member;

a plurality of openings that communicates with the flow channel and that is arranged to extend along at least 30% of the length (l) of the piercing member and each opening of the plurality of openings extends at least 50% of the maximum width of the piercing member to ensure that at least part of the plurality of openings is located substantially adjacent to the innermost side of said sealing member when the device is in use, each of the openings sized to allow a passage of liquids;

an elastic retractable sleeve arranged to at least partly cover and seal the plurality of openings when the device has not been inserted into said sealing member of said fluid container, wherein said sleeve is arranged to abut against the outermost side of said sealing member when the device has been inserted into said sealing member of said fluid container and be retracted as the piercing member penetrates more deeply into said sealing member such that the retractable sleeve

will cover and seal only a portion of the plurality of openings which are located outwards of the outermost side of the sealing member when the device is in use and thus prevent any fluid from leaking out of said plurality of openings; and

an air inlet disposed on the elongated body.

2. The device according to claim **1**, wherein the plurality of openings extends substantially along the entire length (l) of the piercing member.

3. The device according to claim **2**, wherein the plurality of openings are uniformly spaced along the length (l) of the piercing member.

4. The device according to claim **1**, wherein the plurality of openings are uniformly spaced along the length (l) of the piercing member.

5. The device according to claim **1**, wherein the plurality of openings is arranged to extend along at least 50% of the length (l) of the piercing member.

6. The device according to claim **1** further comprising connecting means to connect it to the fluid container.

7. The device according to claim **6**, wherein the connecting means comprises multiple resilient arms configured to slidably engage a rim on the fluid container.

8. The device according to claim **1** further comprising a ruled scale on the piercing member.

9. The device according to claim **1**, wherein the plurality of openings is disposed behind the tip of the piercing member.

10. The device according to claim **1**, wherein the plurality of openings is arranged to extend along at least 70% of the length (l) of the piercing member.

11. The device according to claim **10**, wherein the plurality of openings are uniformly spaced along the length (l) of the piercing member.

12. A sealing member for sealing an inlet or an outlet of a fluid container, comprising a device that is integrally formed with the sealing member or releasably or non-releasably connected thereto, wherein said device comprises

a piercing member having a tip for penetrating the sealing member;

an elongated body defining a longitudinal flow channel through which a fluid may flow into and/or out of the fluid container, the elongated body having a greater width than the width of the piercing member;

a plurality of openings that communicates with the flow channel and that is arranged to extend along at least 30% of the length (l) of the piercing member and each opening of the plurality of openings extends at least 50% of the maximum width of the piercing member to ensure that at least part of the plurality of openings is located substantially adjacent to the innermost side of said sealing member when the device is in use, each of the openings being sized to allow for passage of liquids;

an elastic retractable sleeve arranged to at least partly cover and seal the plurality of openings when the device has not been inserted into said sealing member of said fluid container, wherein said sleeve is arranged to abut against the outermost side of said sealing member when the device has been inserted into said sealing member of said fluid container and be retracted as the piercing member penetrates more deeply into said sealing member such that the retractable sleeve will cover and seal only a portion of the plurality of openings which are located outwards of the outermost side of the sealing member when the device is in use and thus prevent any fluid from leaking out of said plurality of openings; and

an air inlet disposed on the elongated body.

13. The sealing member according to claim **12**, wherein the device is slidably mounted on the sealing member so that the plurality of openings of the device may be opened and closed by sliding the device back and forth with respect to the sealing member.

14. A fluid container, comprising a sealing member according to claim **12** or **13**.

15. The device according to claim **12**, wherein said device is releasably connected to said sealing member.

16. The device according to claim **15**, wherein the plurality of openings are uniformly spaced along the length (l) of the piercing member.

17. The device according to claim **15**, further comprising connecting means to connect it to the fluid container.

18. The device according to claim **12**, wherein said sealing member is a rubber, plastic, or elastomeric bung, stopper, membrane, or puncturable.

19. A device for transferring a fluid to a fluid container, or from a fluid container, or both to and from a fluid container, wherein said fluid container comprises a sealing member having an innermost side and an outermost side, the device comprising:

a piercing member having a tip for penetrating the sealing member;

an elongated body defining a longitudinal flow channel through which a fluid may flow into and/or out of the fluid container, the elongated body having a greater width than the width of the piercing member;

an opening that communicates with the flow channel and that is arranged to extend along at least 30% of the length (l) of the piercing member and the opening extends at least 50% of the maximum width of the piercing member to ensure that at least part of the opening is located substantially adjacent to the innermost side of said sealing member when the device is in use;

an elastic retractable sleeve arranged to at least partly cover and seal the opening when the device has not been inserted into said sealing member of said fluid container, wherein said sleeve is arranged to abut against the outermost side of said sealing member when the device has been inserted into said sealing member of said fluid container and be retracted as the piercing member penetrates more deeply into said sealing member such that the retractable sleeve will cover and seal only a portion of the opening which is located outwards of the outermost side of the sealing member when the device is in use and thus prevent any fluid from leaking out of the opening; and

an air inlet disposed on the elongated body.

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